Dr. John B. Mazur, M.D.
Specializing in Spinal Surgery
Certified by the American Board of Neurological Surgery

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs,

I am writing to you in regards to Docket #97N-484S. For the past twenty-five years or so, I have been utilizing human allograft in surgery of the cervical spine. In that time period I have probably utilized this material in over 1,000 cases. I have had no cases of significant complications caused by the allografts.

At one time I even harvested my own allograft and had it processed by the hospital. We charged nothing for the allograft and this decreased the cost of medical care. Since then, regulated bone banks have appeared and this did increase the cost of these products. I fear that further regulation will further increase the cost to the consumer. This increased cost will not be balanced by an increased safety by regulation. I strongly feel that allograft material should not be regulated as a medical device.

Thank you for your consideration.

Sincerely yours,

John B. Mazur, MD

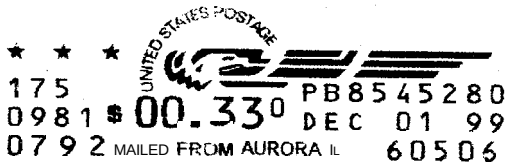
JBM:jaa/12-1-99

302 Randall Road
Suite 308
Geneva, IL 60134
630-262-1210

1315 Highland Ave.
Suite 105
Aurora, IL 60506
630-892-2797
FAX 630-859-2378

610 Plaza **Drive**
Unit #4
Sycamore, IL 60178
815-895-8422

The Spine Specialist SC.
1315 N. Highland Ave. Suite 105
Aurora, IL 60506



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